Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

General Hospital Devices Branch
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation

Preface

Public Comment

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Background

This guidance document was developed as a special control guidance to support the classification of the implantable radiofrequency transponder system for patient identification and health information into class II (special controls). The device is intended to enable access to secure patient identification and corresponding health information in humans. This guidance is issued in conjunction with a Federal Register notice announcing the classification of implantable radiofrequency transponder system for patient identification and health information.

This guidance document describes a means by which implantable radiofrequency transponder systems for patient identification and health information may comply with the requirement of class II special controls. Designation of this guidance document as a special control means that manufacturers of implantable radiofrequency transponder systems for patient identification and health information who follow the recommendations listed in this document, before introducing their device into commercial distribution in the United States, will also be able to market their device without being subject to the premarket notification requirements of section 510(k) of the Act.

Section 510(m) of the Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of

the device. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance or equivalent measures to address the risks identified in this guidance. Thus, persons who intend to market a device of this type do not need to submit a premarket notification to FDA and receive agency clearance prior to marketing the device, but as a class II device, the device must comply with the other applicable general and special controls (Section 513(a)(1)(B)).

Following the effective date of a final rule exempting the device, manufacturers of implantable radiofrequency transponder systems for patient identification and health information will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.[1] If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues**" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

2. Scope

The scope of this document is limited to the following device as described in 21 CFR 880.6300 Implantable Radiofrequency Transponder System for Patient Identification and Health Information (product code: NRV):

[1] We recommend that you document how you have addressed the recommendations in your design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code which is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.

3. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the Implantable Radiofrequency Transponder System for Patient Identification and Health Information addressed in this document. FDA recommends the following measures to mitigate the identified risks in this guidance, as shown in the table below.

Identified risk	**Recommended mitigation measures (See the corresponding subheading in section 4)**
Adverse Tissue Reaction	A. Biocompatibility J. Sterility L. Labeling
Migration of implanted transponder	D. Migration Testing of Implanted Transponder
Compromised Information Security	B. Information Security Procedures (Design and Validation)
Failure of implanted transponder	E. Performance Testing of Implanted Transponder L. Labeling
Failure of Inserter	F. Performance Testing of Inserter
Failure of electronic scanner	G. Performance Testing and Hazard Analysis of Electronic Scanner C. Software Validation L. Labeling
Electromagnetic Interference	H. Electromagnetic compatibility L. Labeling
Electrical Hazards	I. Electrical Safety performance testing L. Labeling
Magnetic Resonance Imaging Incompatibility	K. Magnetic Resonance Imaging Compatibility L. Labeling
Needle stick	L. Labeling

4. Recommended Mitigation Measures

FDA believes that conformance with this guidance document, when combined with the general controls of the Act, will provided reasonable assurance of the safety and effectiveness of the implantable radiofrequency transponder system for patient identification and health information. We recommend that you (the manufacturer) evaluate your device as described below and, where appropriate, document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).

A. Biocompatibility

We recommend that you ensure the biocompatibility of the patient-contacting parts of your device by following the tests in the:

- International Standard Organization (ISO) standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

B. Information Security Procedures (Design and Validation)

When discussing the issue of medical devices that store, access, and/or transfer information externally, you should address the concept of information security. Information security is the process of preventing the modification, misuse or denial of use, or the unauthorized use of that information. We recommend that your specifications for a compatible database address the following four components of information security: Confidentiality, Integrity, Availability, and Accountability (CIAA).

- **Confidentiality** means the characteristic of data and information being disclosed only to authorized persons, entities and processes at authorized times and in the authorized manner. (The assurance that no unauthorized users have access to the information.)

- **Integrity** means the characteristic of data and information being accurate and complete and the preservation of accuracy and completeness. (The assurance that the information is correct (accurate and complete) - that is, it has not been improperly modified.)

- **Availability** means the characteristic of data, information and information systems being accessible and usable on a timely basis in the required manner. (The assurance that the information will be available when needed.)

- **Accountability** is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

C. Software Validation

We recommend that you validate the software in your device by referring to the following guidance:

- **Guidance for FDA Reviewers and Industry Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**
  http://www.fda.gov/cdrh/ode/57.html
- **General Principles of Software Validation; Final Guidance for Industry and FDA Staff**
  http://www.fda.gov/cdrh/comp/guidance/938.html

D. Migration Testing of Implanted Transponder

We recommend that you conduct testing of the implanted transponder to demonstrate that the transponder will not migrate after implantation.

E. Performance Testing of Implanted Transponder

We recommend that you conduct testing of the transponder that will demonstrate that under conditions of use the transponder sends an identification (ID) code and that the ID code is correct. The testing should address loss or corruption of the data, latency and through-put, and be coordinated with the electromagnetic compatibility (EMC) performance of the implant, scanner and wireless data link.

F. Performance Testing of Inserter

We recommend that you demonstrate the functionality of the insertion device by conducting testing that demonstrates that inserter can properly implant the transponder.

G. Performance Testing and Hazard Analysis of Electronic Scanner

We recommend that you address the functionality of the electronic scanner by conducting performance testing and hazard analysis that demonstrate the scanner utility in reading the transponder identification code.

H. Electromagnetic Compatibility

We recommend that you demonstrate the basic EMC of the device (i.e., transponder and scanner together) by performing EMC testing in accordance with the following FDA-recognized standard:

- IEC 60601-1-2 (Second Edition, 2001) Medical electrical equipment - Part1: General requirements for safety; Electromagnetic compatibility - Requirements and Tests, or its equivalent.

I. Electrical Safety Performance Testing

We recommend that you demonstrate the electrical safety of your device by following the testing in:

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety

J. Sterility

We recommend that the transponder and inserter be sterile with a sterility assurance level of 10^{-6}. We also recommend that you address the sterility of your device by reviewing the following:

- Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA. http://www.fda.gov/cdrh/ode/guidance/361.html.

K. Magnetic Resonance Imaging Compatibility

We recommend that you demonstrate the magnetic resonance imaging compatibility of your device by following:

- ASTM F2052-02 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

- ASTM F2182-02a Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

- ASTM F2213-04 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

- ASTM F2119-01 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

In addition, you should also address the EMC concerns for implant exposure to the significant magnetic and radiofrequency emissions from MRI, including concerns for implant malfunction or damage from MRI exposure and the use of the scanner during MRI procedures.

L. Labeling

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use.[2]

[2] Final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce.

We recommend that instructions delineate the technological features of the specific device and how the device is to be used on patients. We recommend that the instructions encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner. If there are any precautions or warnings, which relate to packaging or sterility, these should be repeated on the package labels.

We also recommend that you provide after surgery care instructions to the patient. See also **Guidance on Medical Device Patient Labeling**, http://www.fda.gov/cdrh/ohip/guidance/1128.html.

5. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a Class II device from the requirement of premarket notification is based on the existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 880.9 specifies the limitations to exemption. If any of these limitations apply, your device is not exempt and you must submit a premarket notification.